This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS /
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: WO 99/37247 (11) International Publication Number: A1 A61F 2/16 (43) International Publication Date: 29 July 1999 (29.07.99)

(21) International Application Number:

PCT/GB99/00216

(22) International Filing Date:

22 January 1999 (22.01.99)

(30) Priority Data:

9801214.9

22 January 1998 (22.01.98) GB

(71) Applicant (for all designated States except US): DUCK-WORTH & KENT LIMITED [GB/GB]; Terence House, 7 Marquis Business Centre, Royston Road, Baldock, Hertfordshire SG7 6XL (GB).

(72) Inventor; and

- (75) Inventor/Applicant (for US only): WALDOCK, Terence, Arnold [GB/GB]; The Manor House, Church Road, Meppershall, Bedfordshire SG17 5NA (GB).
- (74) Agent: THOMSON, Roger, Bruce; W.P. Thompson & Co., Eastcheap House, Central Approach, Letchworth, Hertfordshire SG6 3DS (GB).

(81) Designated States: AU, BR, CA, GB, JP, RU, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

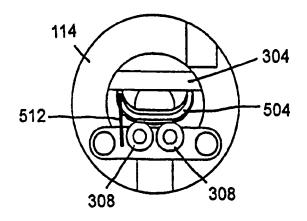
Published

With international search report.

(54) Title: LENS INJECTOR

(57) Abstract

An instrument for the insertion of an intraocular lens into an eye comprises a body portion, a nose portion (114) through which runs a passage for the lens to pass to a dispensing tip, and a plunger. The nose portion is preferably pivotally connected to the body portion so that the barrel can be broken open for the placement of the lens into the nose portion. The lens (504) is preferably placed on two spaced parallel nose pins (308) to facilitate its folding. A cross pin (304) preferably straddles the nose pins (308) and under which the lens is arranged to pass, to prevent lifting and tilting of the lens.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
ΑT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
ΑZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
ВJ	Benin	(E	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL.	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	1T	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
BE	Estonia	LR	Liberia	SG	Singapore		

PCT/GB99/00216 WO 99/37247 1

LENS INJECTOR

This invention relates to instruments for inserting an intraocular lens into an eye. It is necessary in certain 5 ophthalmic surgical procedures to insert an intraocular lens through a small incision, such as in the phacoemulsification technique of removing cataracts.

One particular instrument for carrying out this procedure is described in US patent 4,681,102 (Bartell). In this 10 instrument the intraocular lens is placed within a hinged, generally cylindrical load chamber having a pair of flanges. The load chamber is folded around the intraocular lens, so that the lens itself becomes folded or rolled along its length. The load chamber is fitted into an injector portion 15 which has a slot which is keyed to the flanges of the load The injector portion and load chamber are then chamber. fitted into an insertion cone which defines a lumen for passage of the lens through the lumen. A plunger which is inserted into the injector portion is then used to push the 20 lens through the lumen and into the eye. The folded intraocular lens opens out into its flattened form as it emerges from the distal end of the insertion cone.

In US 4,681,102 the insertion cone, the load chamber and the injector portion are all separate pieces, preferably made 25 of moulded plastics material, so that they can be disposed of after a single use. This means of course that there is a continuing expense in the use of the instrument and it is also necessary to have available a supply of parts.

Our patent application PCT/GB98/03917 describes an 30 instrument for the insertion of intraocular lenses which does not involve the use of disposable parts. In that instrument

the intraocular lens is not folded within a load chamber. It is one object of the aforesaid invention to enable the lens to be placed easily into the instrument for subsequent injection. The lens is inserted into the instrument in a flat state and it is the configuration of the lumen in the nose portion of the instrument which folds the lens as a plunger pushes the lens forward through the nose portion.

It is an object of the present invention to provide an instrument for the insertion of intraocular lenses in which the lens which is to be inserted is laid on support means which not only serves as a guide for the lens in its onward movement through the nose, but also facilitates the positioning of the lens correctly within the instrument.

The instrument of the present invention, dispensing as 15 it does with disposable parts, is adapted for repeated use, with appropriate sterilisation, and can be made for example of titanium or a titanium alloy. One can produce an extremely accurately machined instrument which is easy both to load and to use.

In accordance with the present invention there is provided an instrument for the insertion of an intraocular lens into an eye, which comprises a body portion, a nose portion forward of the body portion and having a lumen through which the lens is arranged to pass, and a plunger moveable through the body portion and the nose portion, wherein there is provided in the nose portion support means for the lens which defines an undulating support surface for the lens.

Preferably, the support means comprises two parallel spaced pins whose surfaces define the undulating support 30 surface for the lens.

The pins are preferably set into the rear end of the nose

portion of the instrument.

The use of an undulating support surface for the lens, for example as provided by the two pins, is that this configuration also helps to centralise the forceps which are 5 used to place the lens within the instrument. Additionally, the use of two spaced pins or an equivalent surface configuration helps to guide the lens into the funnel or lumen through which the lens has to pass. The space between the two pins, or the valley in some other equivalent configuration, 10 allows the lens more easily to fold about its centre as it is pushed forward through the nose portion of the instrument.

Preferably the instrument includes a cross pin extending transversely across the path of the lens and beneath which the lens is arranged to pass. Preferably, the cross pin straddles 15 the nose pins. The main purpose of the cross pin is to prevent lifting or tilting of the lens both on insertion into the nose and in its passage towards the tip.

The use of this special support for the lens can be embodied in any form of lens injector. Although it is 20 particularly appropriate for use with the types of lens injector shown in our patent application PCT/GB98/03917 where the nose portion of the instrument is shown pivotable relative to the body portion of the instrument, the present invention is equally applicable to other types of lens injector, for 25 example a straight injector in which the lens is inserted through a "window" or under a flap in the nose portion, or indeed in the body portion.

In order that the invention may be more fully understood, a number of preferred embodiments of lens injector in 30 accordance with the invention will now be described by way of example and with reference to the accompanying drawings. In

the drawings:

WO 99/37247

- Fig. 1a shows a plan view of a first embodiment of lens injector, in the closed position;
 - Fig. 1b is the side view of the injector of Fig. 1a;
- Fig. 2 shows the injector according to Fig. 1b, but with the injector in the opened position;
 - Fig. 3 shows internal details of the lens injector of Figs. 1 and 2, and is shown with the plunger fully depressed;
- Fig. 4 shows the lens injector of Fig. 3, in side view, 10 and with the plunger retracted;
 - Fig. 5 shows the lens injector of Fig. 4, but from below;
 - Fig. 6 is a plan view of the main body of the lens injector;
- Fig. 7 is the side view of the main body of the lens 15 injector shown in Fig. 6;
 - Fig. 8 is a side view of the plunger and push rod of the lens injector;
 - Fig. 9 is the view of the plunger and push rod of Fig. 8, from below;
- 20 Fig. 10 is the view on arrow A in Fig. 9;
 - Fig. 11 is the front end view of the push rod, viewed from the left-hand end as shown in Fig. 10;
 - Fig. 12 is a plan view of the two-part nose assembly of the lens injector;
- Fig. 13 is the side view of the nose assembly shown in Fig. 12;
 - Fig. 14 is the underneath plan view of the nose assembly shown in Figs. 12 and 13;
- Fig. 15 shows the front portion of the nose assembly, in 30 top plan view;
 - Fig. 16 shows the front portion of the nose assembly of

WO 99/37247 PCT/

5

Fig. 15, in side view;

Fig. 16a is the view on the right-hand end of Fig. 16;

- Fig. 17 shows the front portion of the nose assembly of Figs. 15 and 16, in underneath plan view;
- Figs. 18, 19 and 20 are plan, side and underneath plan views respectively of the outer sleeve which in combination with the front portion shown in Figs. 15 to 17 forms the nose assembly shown in Figs. 12 to 14;
- Fig. 21 is a side view of a second embodiment of lens 10 injector in accordance with the invention, with the plunger retracted;
 - Fig. 22 shows the lens injector of Fig. 21, but from below;
- Fig. 23 is the top plan view of the lens injector of Fig. 15 21, with the plunger fully depressed;
 - Fig. 24 is the side view of the front piece of the nose portion of the lens injector;
 - Fig. 25 is the end view taken in the direction of the arrow XXV in Fig. 24;
- Fig. 26 is the plan view of the front piece of the nose portion shown in Fig. 24;
 - Fig. 27 is the side view of the complete nose assembly of the nose injector, including an outer sleeve;
- Fig. 28 is the end view taken in the direction of the 25 arrow XXVIII in Fig. 27;
 - Fig. 29 is the top plan view of the nose assembly of Fig. 27;
 - Fig. 30 is the underneath plan view of the nose assembly shown in Fig. 27;
- Fig. 31 shows one of the pins used in the nose assembly;
 Fig. 32 is the top plan view of a modified embodiment of

nose assembly, illustrating the use of a cross pin in the lens passage;

- Fig. 33 is the side view of the nose assembly of Fig. 32;
- Fig. 34 is the end view of the nose assembly of Figs. 32 5 and 33 taken from the right-hand end of Fig. 33;
 - Fig. 35 is the side view of an alternative embodiment of nose for a lens injector according to the invention;
 - Fig. 36 is the top plan view of the nose of Fig. 35;
- Fig. 37 is the end view of the nose of Fig. 35 taken from 10 the right-hand end of Fig. 35;
 - Fig. 38 shows the pin support which is fitted into the rear end of the nose of Figs. 35 to 37;
 - Fig. 39 shows the pin support of Fig. 38 fitted with two nose pins to make a nose pin assembly;
- Fig. 40 is a side view of the nose pin assembly of Fig. 39;
 - Fig. 41 is the sectional view on XLI-XLI in Fig. 39;
 - Fig. 42 is a side view of a modified plunger and push rod;
- Fig. 43 is a plan view from below of the plunger and push rod of Fig. 42;
 - Fig. 44 is a top plan view of the push rod of Figs. 42 and 43;
- Fig. 45 is a side view of the push rod of Fig. 42 on an 25 enlarged scale;
 - Fig. 46 is an enlarged plan view of the tip of the push rod of Fig. 44;
 - Fig. 47 is an enlarged side view of the tip of the push rod of Fig. 45;
- Fig. 48 shows a lens with haptics positioned on a loading plate;

Fig. 49 shows the picking up of the lens from the loading plate with forceps;

Fig. 50 shows the placing of the lens onto the nose pins;

Fig. 51 shows the forceps pushed fully forward;

5 Fig. 52 shows the forceps being removed from the chamber; and,

Fig. 53 shows the lens correctly positioned for injection.

The present invention is described hereinafter in relation to intraocular lens injectors of the general type described and shown in our patent application PCT/GB98/03917, which has a nose portion which can be "broken open" in like manner to a shotgun barrel. However, it is to be understood that the present invention is applicable to other types of intraocular lens injectors and that it is described in relation to this particular type of lens injector by way of example only.

A first embodiment of intraocular lens injector is shown generally in Figs. 1a, 1b and 2. It will be seen that the 20 injector essentially comprises a body portion 10, a plunger 12 and a nose portion 14. Each of these parts will be described in more detail hereinafter. As will be apparent from these Figures, the nose portion 14 can be "broken open" in like manner to a shotgun barrel. In the closed position 25 as shown in Figs. 1a and 1b the nose portion 14 is coaxial with the main body 10 and the plunger 12. Fig. 2 shows the nose portion broken open. The body portion 10 has a finger 16 projecting from the front end of the body at the bottom of the body, and a pivot pin 18 extends through the nose portion 30 and the finger 16 to provide the pivotal mounting. As shown in Fig. 2, the nose portion is pivotable through 90° from the

WO 99/37247 PCT/GB99/00216

8

open position to the closed position and vice versa. It will be seen in Fig. 1a that the nose portion and body portion are each provided with an engraved marking 20, with the markings being in alignment when the nose portion is closed. These 5 lines provide an indication to the user as to where the nose portion should be pushed in order to open the nose.

Although the method of operation of the instrument will be described in more detail hereinafter, it will be helpful briefly to describe the method of use with reference to Figs. 10 la, 1b and 2. From the closed position shown in Figs. la and 1b the injector is opened by holding the instrument with the engraved lines 20 uppermost and pushing down on the nose 14. With the nose portion thus opened, the intraocular lens to be inserted into the eye is placed into the nose in the direction 15 of the arrow A in Fig. 2, using suitable forceps. is slid forward on the flat face at the bottom of the nose, as will become evident from the later drawings of this embodiment. In the case of a haptic lens, when the rear haptic is fully into the nose, the nose is closed until it 20 clicks shut. The plunger is then depressed, causing the lens to be ejected from the tip of the nose portion and through the incision in the eye.

Reference is now made to Figs. 3 to 5, which show more details of the lens injector. The nose portion 14 will be 25 described in more detail hereinafter. Suffice it to say here that there is a passage completely through the nose portion which changes in cross-section and configuration from one end of the nose portion to the other. At the distal end the nose portion has a tip 22 through which the lens is ejected. As 30 shown in Fig. 3, when the plunger 12 is fully depressed, the push rod 24 passes out through the tip of the nose portion.

The plunger 12 is slidable within the body portion 10 which is in the form of a cylindrical barrel having a bore therethrough. At two positions along its length the plunger 12 has circumferential grooves 26 (Fig. 8) which carry bushes 5 28 which have the purpose of steadying the plunger 12 as it is moved slidably within the barrel. A spring 30 provides a force against which the plunger is depressed and urges the plunger 12 into its retracted position. The spring 30 is seated at one end against an annular face inside the front end 10 of the barrel and at the other end against a forwardly facing annular surface 32 (Fig. 8) at the forward end of the plunger The underside of the plunger 12 is provided with a 12. longitudinally extending groove 34. A stop pin 36 which extends radially through the wall of the body portion 10 at 15 its rearward end projects into the groove 34 in the plunger 12 and serves as a stop to limit movement of the plunger both forwards and rearwards.

The push rod which is indicated generally at 24 is fitted into the forward end of the plunger 12. A hole is drilled in 20 the plunger and the push rod is held in position by friction welding. The push rod 24 is of such a length that when the plunger 12 is fully retracted, as shown in Figs. 4 and 5, the leading end of the push rod lies within the forward end of the body portion 10 and rearwardly of the nose portion 14. This enables the nose portion 14 to be broken open without danger of striking against the end of the push rod. As shown most clearly in Fig. 4, the leading end of the push rod 24 is located at the bottom of a counterbore 38 through the forward end of the body portion 10. Referring now to Figs. 6 and 7, 30 these show the body portion 10 in more detail. In particular, they show the forwardly projecting finger 16 at the leading

end of the barrel and which is provided with a hole 40 therethrough to receive the pivot pin 18. At the rear end of the barrel, in Fig. 7, is shown a hole 42 into which the stop pin 36 is fitted.

- Figs. 8 to 11 show more details of the plunger 12 and push rod 24. The leading end of the push rod 24 is specially shaped, as shown most clearly in Figs. 10 and 11, in order to enable the lens to be folded and pushed reliably and effectively through the nose portion and into the eye. The 10 lens injector of the present invention can be used both with plate-type lenses and with haptic lenses. The shape of the push rod at its leading end is designed so that it will slide through the lumen in the nose portion 14 by virtue of its curved undersurface and yet will safely guide the lens through 15 the lumen.
- Figs. 12 to 14 show details of the nose assembly which is indicated generally at 14. The nose assembly is made in two parts, a front piece which is shown in Figs. 15 to 17 and an outer sleeve which is shown in Figs. 18 to 20. The front 20 portion shown in Figs. 15 to 17 includes the tip 22 which is cut off at 45° at the distal end. Behind the generally cylindrical but slightly tapering tip 22 is a frusto-conical portion 44. To the rear of that is a shaped portion 46 which includes a "bullet-shaped" recess 48 and a tapered bore 25 indicated at 50 in Fig. 16. Shaping the rear portion 46 in this way causes the lens which is inserted here to be folded as it is pushed forward by the push rod into the cylindrical passage 52 through the tip 22. The folding of the lens is effected solely by the shape of the encircling passageway and 30 only begins when the lens begins its movement through the nose portion.

The outer sleeve shown in Figs. 18 to 20 comprises a generally cylindrical sleeve 54 which fits over the rear portion 46 of the front piece of the nose and which abuts the annular rearwardly facing surface 56 of the frusto-conical 5 portion 44. The outer sleeve 54 is provided with a hole 56 therethrough which receives the pivot pin 18. The rearward end of the sleeve 54 is provided with a rearwardly projecting spigot 58 which is recessed as indicated at 60 to serve as a latch for a locking pin when the nose portion is closed 10 against the body portion.

The whole instrument which comprises the lens injector is preferably made of titanium or a titanium alloy. This material can be machined to great accuracy and with a good surface finish. It can also be easily sterilised for repeated 15 use.

The injector shown in Figs. 21 to 31 essentially comprises a body portion 110, a plunger 112 and a nose portion 114. The nose portion 114 can be "broken open" in like manner to a shotgun barrel, as described in the preceding embodiment. 20 In the closed position, as shown in Figs. 21 to 23, the nose portion 114 is coaxial with the main body 110 and the plunger 112. As will be described in more detail hereinafter, with the plunger 112 retracted as shown in Figs. 21 and 22, the nose portion 114 is broken open and the lens which is to be 25 inserted into the eye is placed in the nose, using suitable forceps. In the present embodiment, the lens is inserted into the open rear end of the nose portion of the injector, using suitable forceps. The nose is then closed until it clicks shut. Subsequently the plunger is depressed, causing the lens 30 to be ejected from the tip of the nose portion and through an

incision in the eye.

PCT/GB99/00216 WO 99/37247 12

In the present embodiment, the nose portion 114 is provided with a "window" 116 which is open to the chamber into which the lens is placed. This is simply a viewing window which enables the surgeon to see the lens in place. It also 5 enables the surgeon to check that the rear haptic of an intraocular lens which has haptics is not caught by the front end of the plunger 112.

Reference is now made to Figs. 24 to 26, which show more details of the front piece of the nose assembly. The nose 10 assembly is made in two parts, a front piece which is shown in Figs. 24 to 26, and an outer sleeve which is shown in combination with the front portion in Figs. 27 to 30. front piece shown in Figs. 24 to 26 includes a tip 118 which is cut off at 45° at the distal end. The tip has a 15 cylindrical internal bore 120 of for example 2.2 mm diameter, with the external surface being generally cylindrical but slightly tapering. To the rear of the tip 18 is a frustoconical portion 122. To the rear of that is a stub portion 124 which has a cylindrical external surface. The stub 20 portion 124 has an internal tapered bore 126 which decreases in diameter from the rearward end towards the internal bore 120 in the tip 118. The bore 126 and the bore 120 together form a passage which is of decreasing cross-section from rearward end to forward end, but which is of circular cross-25 section throughout.

As shown in Figs. 24 to 26, a pair of cylindrical holes 128 are bored into the stub portion 124 and frusto-conical portion 122 of the nose. These bores 128 extend parallel to the longitudinal axis of the nose portion. The forward end 30 of each bore 128 lies approximately halfway along the length of the frusto-conical portion 122 and is contiguous at its

periphery with the bore through the nose portion. The rearward end of each hole 128 exits in the sloping surface of the tapered bore 126.

As will be seen most clearly from Fig. 24, there is a 5 transition zone in the internal bore, between the rearward tapering bore 126 and the forward cylindrical bore 120, within the frusto-conical portion 122. This transition bore 130 is tapered, but with a lesser taper than that of the rearward bore 126. The front end of each of the holes 128 "merges" 10 with this transitional bore 130.

As will be seen from Figs. 25 and 26, the two holes 128 are spaced apart, each at the same distance from the central vertical plane through the nose portion. They are thus symmetrically positioned in relation to the throughbore 126, 15 130, 120. Each of the holes 128 shown in Figs. 24 to 26 is fitted with a cylindrical pin 132 which is shown in Fig. 31. Each pin 132 is cylindrical but has a chamfered rear end 136. A pin 132 is press-fitted into each of the holes 128 in the front piece of the nose portion. The rear end of each pin 20 132, when fitted, lies flush with the rearward end of the stub portion 124 of the front piece of the nose assembly. is shown most clearly in Figs. 27 to 30, which show the complete nose assembly consisting of the front piece, the two pins 132 and an outer sleeve 134 which is a press fit over the 25 stub portion 124 of the front piece. The forward end of the sleeve 134 abuts the rearward end face of the frusto-conical portion 122. The outer sleeve 134 is provided with the window 116. This is dimensioned so that in use, as shown most clearly in Fig. 29, the two pins 132 can be seen in their 30 side-by-side position below the window. The pivotal connection of the nose portion to the body portion of the

WO 99/37247

14

instrument has been described earlier and is not repeated here.

In use, the intraocular lens which is to be inserted into the eye, whether with or without haptics, is inserted into the 5 nose portion of the injector by first pivoting open the nose assembly and then inserting the lens, using forceps, from the rear end of the nose assembly through the open aperture which Using the forceps, the lens is laid upon the two pins 132 in a sufficiently forward position that the rear 10 haptic of the lens is forward of the rearward end of the nose assembly, so that it does not become caught when the nose assembly is closed to the main body. The provision of the two spaced pins 132 lends itself to the use of forceps to insert the lens. By using a pair of forceps which are 15 essentially T-shaped in cross-section, the stem of the T can be slid between the two pins which will automatically centre the forceps within the chamber and guide the forceps and the lens forward until the lens is released and the forceps are withdrawn. This facilitates the insertion of the lens into 20 the chamber.

In use, the intraocular lens is placed on the upper surface of the two pins. It is therefore supported on the two arcuate surfaces. When the lens is to be injected, the plunger 112 is depressed and the forward end of the plunger 25 enters the chamber in the nose assembly at the level which enables it to slide forward over the pins 132, pushing the lens forward as it travels. As the lens passes forward through the bores 126, 130, 120, so it will be folded by the shape of the encircling circular cross-section passageway.

30 The two pins 132 guide the lens while it passes through the tapering bores 126 and 130, and only terminate their guiding

PCT/GB99/00216

WO 99/37247

function when the lens enters the cylindrical bore 120 in the tip 118. A further feature of this arrangement is that because of the spacing of the two pins 132, with what is effectively a valley between them, as the lens is folded by the encircling walls, this folding is enhanced by a tendency for the central zone of the lens to sink into the valley between the pins and thus to ensure that the folding is symmetrical about the centre.

The whole instrument which comprises the lens injector 10 is preferably made of titanium or a titanium alloy. material can be machined to great accuracy and with a good surface finish. It can also be easily sterilised for repeated use. There are no disposable parts involved. The use of pins 132 is not a problem with a metal instrument, such 15 as one made of titanium. It simply requires two holes to be bored in the nose piece and for the pins then to be fitted before the rest of the nose is assembled. This does not involve any complicated machining operations. However, particularly if alternative materials are used for the 20 instrument, one could replace the pins by an internal configuration for the chamber within the nose assembly which is undulating and shaped to give the guiding and folding functions described above. For example, the lower portion of the internal chamber could be of undulating shape defining two 25 arcuate peaks upon which the lens would be seated, in a manner analogous to that of the two pins 132.

Various alternative means of achieving the same functions as described above will be apparent to those skilled in this art. For example, instead of fitting pins into drilled holes 30 in the nose assembly one could provide a suitably shaped insert arranged to be fitted into the chamber, with this

insert again having a suitable seating surface configuration to provide the positioning and guiding functions described above. However, it has been found that the use of pins is a simple yet effective way of achieving the objects of the invention, particularly with a lens injector which is designed for repeated use.

16

Referring now to Figs. 32 to 34, these show a modification of the nose, which can be used with any of the embodiments of the invention. The nose assembly 200 is here 10 shown without the two nose pins, shown in Figs. 27 to 30, although bores 202 for the nose pins are shown. The pivot pin for the pivoting of the nose assembly is here shown at 204. In this embodiment a pair of bores 206a, 206b are provided through the nose substantially midway along the length of the 15 window 208 to receive a cross pin 210 which when fitted extends transversely across the direction of travel of the lens and at right-angles to the nose pins. The cross pin 210 is positioned straddling the nose pins so that when the lens is set in place using forceps the lens rests on the nose pins 20 with its front edge under the cross pin. When the lens is pushed in under the cross pin, using the forceps, this starts the lens folding process. The cross pin 210 also prevents any possibility of the lens rising or tilting when it is inserted. Specially designed forceps can be used so that when the 25 forceps strike the cross pin the user knows that the lens is correctly positioned and can be released.

After the lens has been set in place, the nose portion is pivoted into its closed position and the plunger can be operated to engage the lens and push it forwards, folding as 30 it advances. The plunger is arranged just to pass beneath the cross pin 210 in its forward movement.

A further advantage of the use of two nose pins is that when using a lens having two haptics, the rear haptic drops down below the adjacent nose pin and therefore is never in the line of movement of the plunger and cannot become caught up 5 by the plunger. This means that the double nose pin arrangement works much better than using a flat receiving plate or other surface for this lens.

Figs. 35 to 41 show yet a further modification to the nose of the lens injector. The nose indicated generally at 10 300 is of generally the same configuration as those described earlier. It includes a pivot pin 302 to enable the barrel to be broken open. In this embodiment however there is no viewing window as in some earlier embodiments. however a cross pin 304 which is rivetted into a pair of bores 15 306a, 306b. In this embodiment, instead of fitting the two nose pins into holes drilled in the material of the nose, the nose pins 308 are carried by a pin support 310 which is itself fitted into the rear of the nose. The pin support 310 has two arcuate recesses 312 into which the nose pins 308 are seated. 20 The pin support 310 also has two bores 314 adjacent to its respective ends, to enable it to be retained in the nose. As shown most clearly in Figs. 39 and 40, the nose pins 308 rest proud of the surface of the pin support 310 to enable the lens to be deposited thereon. The underside 312 of each nose pin 25 308 is shaped, for example by a turning operation, so as to match exactly the contours of the bore through the nose. There is thus intimate contact between the pin surface 312 and the bore.

Reference is now made to Figs. 42 to 47 which show 30 details of an improved tip for the push rod. The push rod, here indicated at 400, is connected to a plunger 402 by a pin

WO 99/37247 PCT/GB99/00216

404. The general construction is similar to that shown in the earlier embodiments. In this embodiment however the plunger 402 and push rod 400 are made of PEEK material. In this embodiment the tip of the plunger is specially shaped in order 5 to assist the engagement between the forward end of the push rod and the lens. The lenses which are used for intraocular purposes are soft and they tend to fold around the tip of the push rod when the plunger is depressed. There is also the problem that the trailing haptic of a haptic lens needs to be 10 located in relation to the push rod and the surrounding part of the instrument so that it is not caught up in any way during the forward movement of the push rod. As can be seen particularly clearly from Figs. 44 to 47, the tip of the push rod 400 is relieved on each side. On the one side there is 15 a relieved zone 406, whereas on the other side there is a relieved zone 408. The latter is substantially twice the length of the former. In addition to the relief at each side of the tip, the front end face 410 of the push rod tip is provided with a recess 412 which extends across the width of 20 the tip and which defines an arcuate surface 414. It is this arcuate surface 414 which engages the lens as the plunger is depressed. The trailing haptic of the haptic lens lies within the longer relieved zone 408 where it is in no danger of being caught up by the tip.

25 Referring now to Figs. 48 to 53, these show the loading procedure for inserting an intraocular lens into the lens injector of the present invention. For this, the lens injector is used in combination with a loading plate 500 and a pair of forceps indicated generally at 502. Initially, an 30 intraocular lens 504 is set on the loading plate 500. The loading plate 500 is provided with a surface slot 506 and with

304.

five pins 508 set on the locus of a circle so that the leading haptic 510 and the trailing haptic 512 on the lens 504 are held by the pins 508. When correctly positioned, the lens 504 overlaps one end of the slot 506. In Fig. 49 there is shown 5 the lower jaw 514 and the upper jaw 516 of the forceps which have tips made of PEEK material. As shown in Fig. 49, the lower jaw 514 of the forceps is placed in the slot 506 of the loading plate, making sure that the trailing haptic 512 is below the jaw 514. With the forceps open, the lower jaw 514 10 is slid forward until it strikes the end of the slot. When the lower jaw 514 is thus correctly registered, the forceps are closed, gripping the lens 504 firmly.

The lens injector is then opened, in the case of the "broken barrel" injector by pushing the front end downwards, 15 exposing the injector chamber. Then, as shown in Fig. 50, the lower jaw 514 of the forceps is placed centrally onto the two nose pins 308 in the chamber. It is necessary to hold the lens firmly with the forceps and to ensure that the forceps are central between the two pins. The forceps are then slid 20 forward in the chamber until they stop by striking the cross pin 304. At this stage the tips of the forceps are opened and the forceps are removed from the chamber, leaving the lens correctly in place. This is shown in Fig. 52. Fig. 53 also shows the lens in the correct fitted position on the pins 308. 25 It will be seen from Fig. 53 that the trailing haptic 512 extends down at the outside of the adjacent nose pin 308 and is therefore free from any danger of being caught up. cross pin 304 against which the forceps strike to limit their inward movement when the lens in fitted is shown in Fig. 53. 30 It can also be seen that the lens passes below the cross pin WO 99/37247 PCT/GB99/00216

CLAIMS

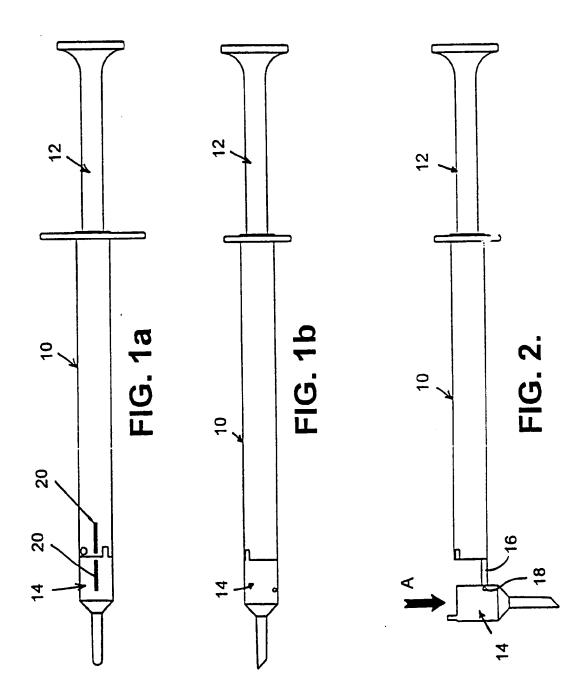
- 1. An instrument for the insertion of an intraocular lens into an eye, which comprises a body portion, a nose portion forward of the body portion and having a lumen through 5 which the lens is arranged to pass, and a plunger movable through the body portion and the nose portion, wherein there is provided in the nose portion support means for the lens which defines an undulating support surface for the lens.
- An instrument according to claim 1, in which the
 support means comprises two parallel spaced nose pins whose surfaces define the undulating support surface for the lens.
 - 3. An instrument according to claim 2, in which the nose pins are set directly into bores made in the material of the nose portion.
- 15 4. An instrument according to claim 2, in which the nose pins are carried by a support member fixed into the rear of the nose portion, with the upper surfaces of the pins being proud of the surface of the support member, and with the undersides of the pins matching the contours of the lumen and 20 being in contact therewith.
 - 5. An instrument according to any preceding claim, which includes a cross pin extending transversely across the path of the lens and beneath which the lens is arranged to pass.
- 6. An instrument according to claim 5 when dependent on claim 2, 3 or 4, in which the cross pin straddles the nose pins.
- 7. An instrument according to any preceding claim, in which the nose portion is hingedly connected to the forward 30 end of the body portion and is movable between open and closed positions in the manner of the opening and closing of a

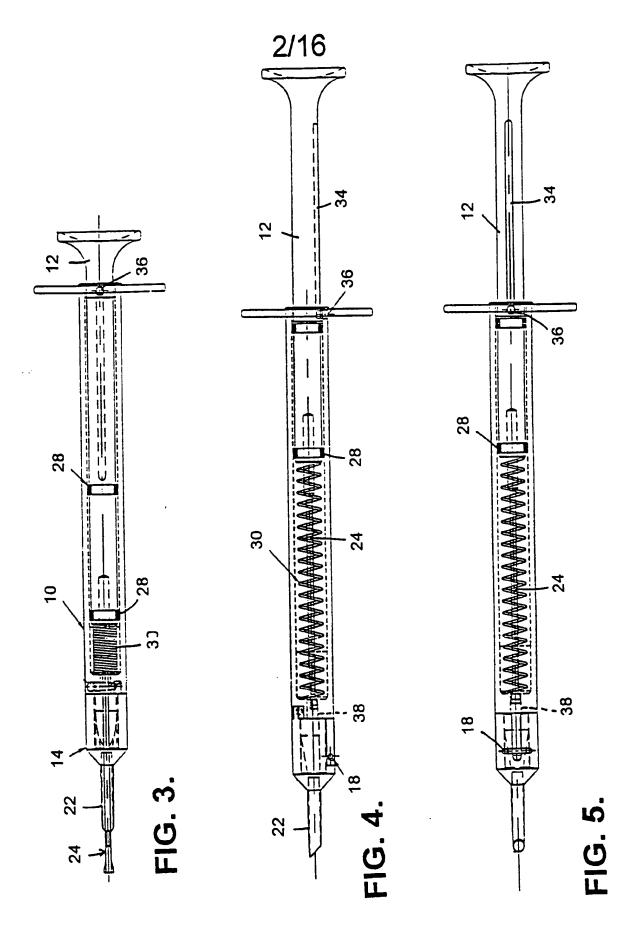
shotgun barrel.

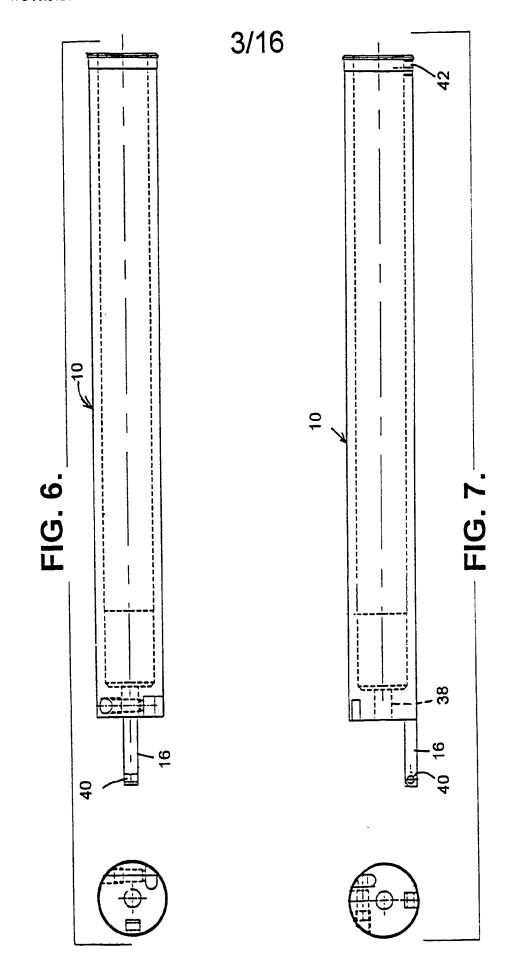
WO 99/37247

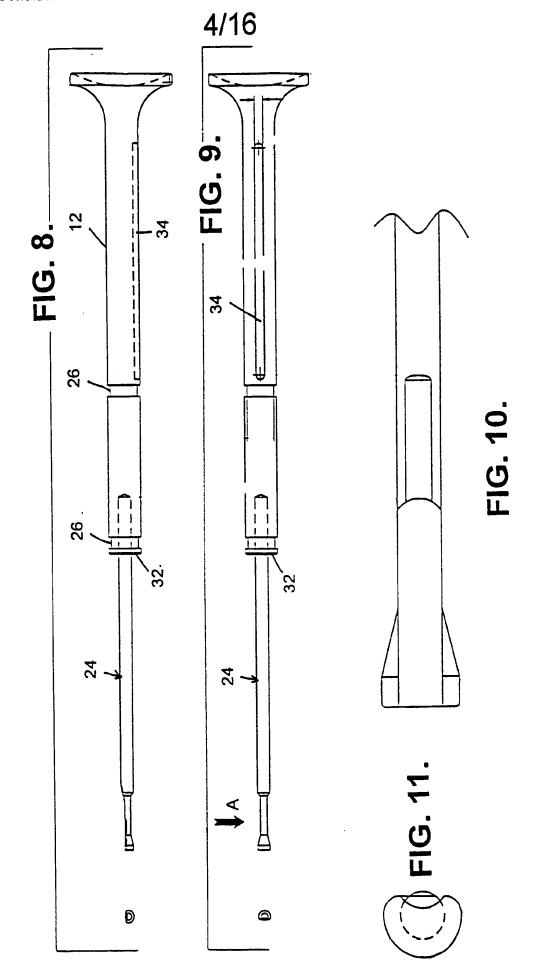
- 8. An instrument according to claim 7, in which the nose portion can be locked into place in the closed position.
- 9. An instrument according to claim 7 or 8, in which 5 the nose portion is pivotally mounted on a forward extension of the body portion, so that the hinge position is forward of the body portion and so that the nose portion, when in the open position, is spaced from the body portion to facilitate the placement of a lens into position in the nose portion.
- 10. An instrument according to any preceding claim, in which the lumen through the nose portion reduces in cross-section in a smoothly continuous manner so that as the lens passes deeper into the nose portion it is constrained to fold for dispensation through the tip of the nose portion.
- 15 11. An instrument according to any preceding claim, in which the nose portion includes a viewing window for the lens.
 - 12. An instrument according to any preceding claim, which is made from titanium or a titanium alloy.
- 13. An instrument according to any preceding claim, in 20 which the plunger has a shaped tip which is relieved on each side.
 - 14. An instrument according to claim 13, in which the length of the relieved zone is greater on one side of the tip than on the other.
- 25 15. An instrument according to claim 13 or 14, in which the front end face of the plunger tip has a recessed portion extending across the width of the tip.
 - 16. An instrument according to claim 13, 14 or 15, in which the plunger is of PEEK material.
- 30 17. An instrument according to any preceding claim in combination with a loading plate for a haptic lens, the plate

being provided with upstanding pins correctly to position the haptics, and with a slot in its upper surface to locate forceps used to grasp the lens.



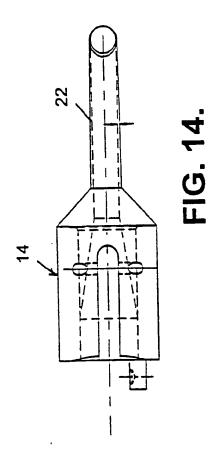


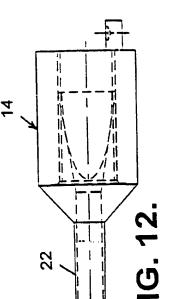


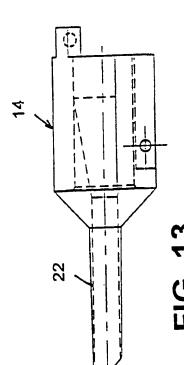


SUBSTITUTE SHEET (RULE 26)









6/16

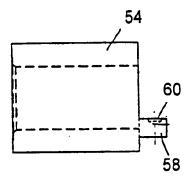
FIG. 17 FIG. 15. 46 22

-IG. 16a.

FIG. 16.

7/16

FIG. 18.



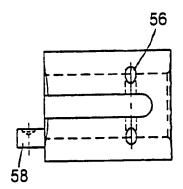


FIG. 20.

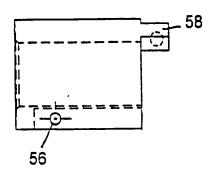
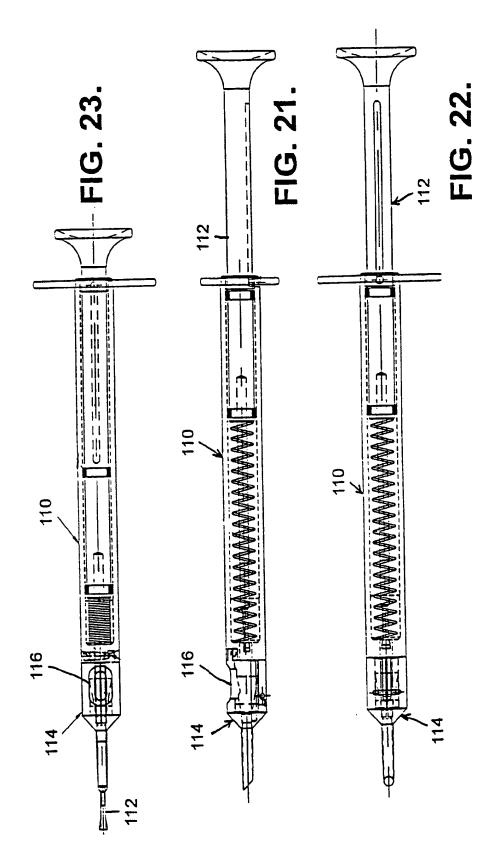
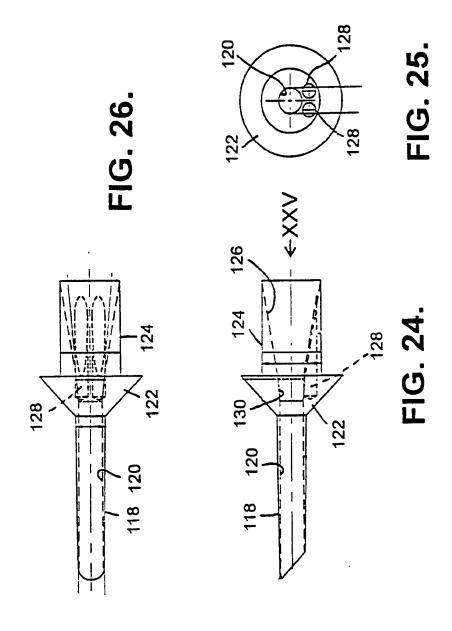


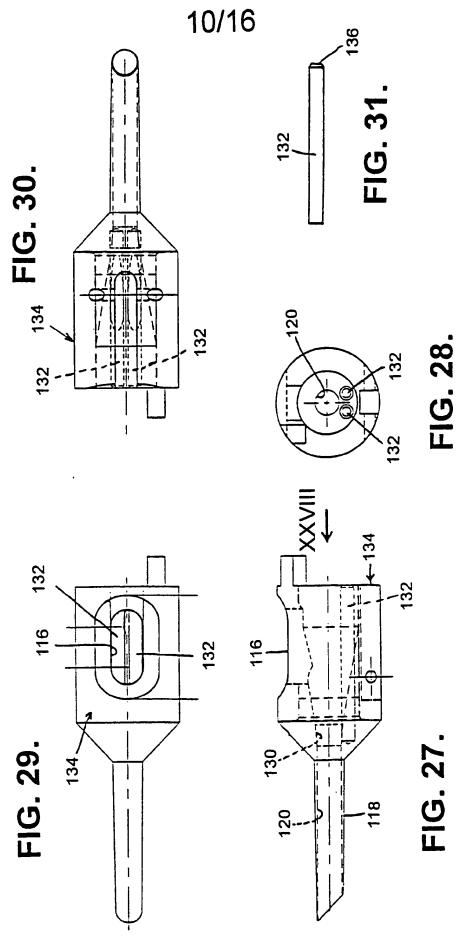
FIG. 19.



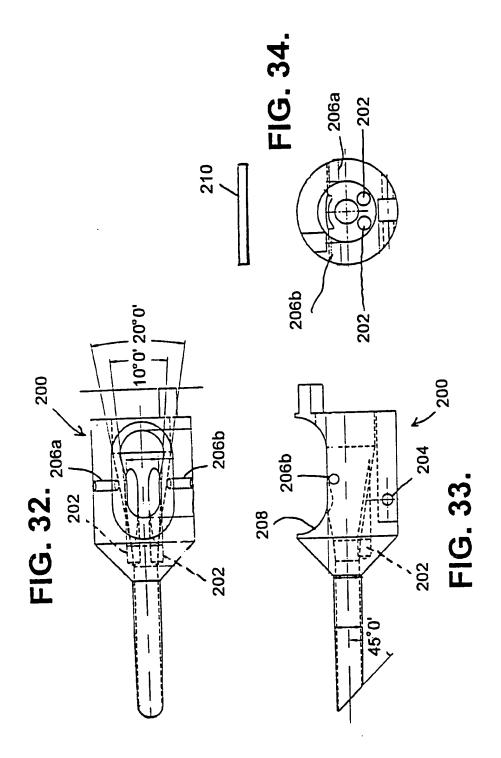
SUBSTITUTE SHEET (RULE 26)

9/16



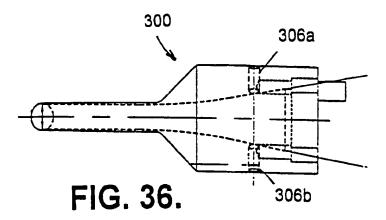


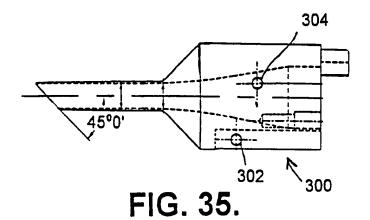
SUBSTITUTE SHEET (RULE 26)



PCT/GB99/00216 WO 99/37247







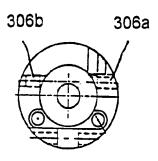
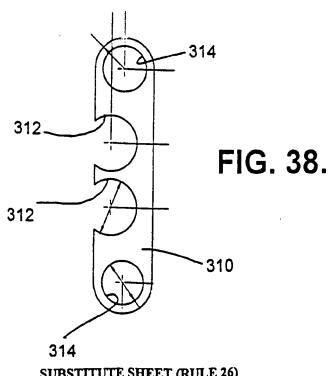
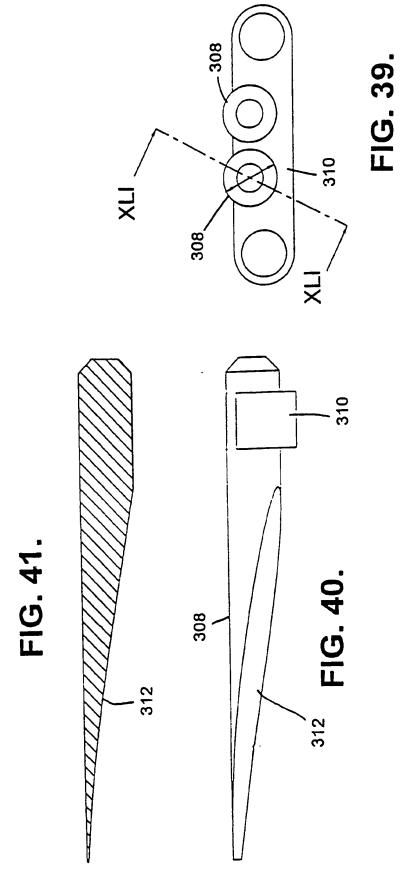


FIG. 37.



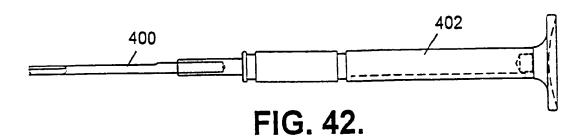
SUBSTITUTE SHEET (RULE 26)

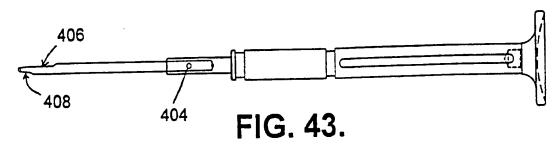
13/16

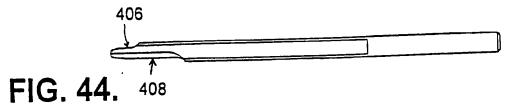


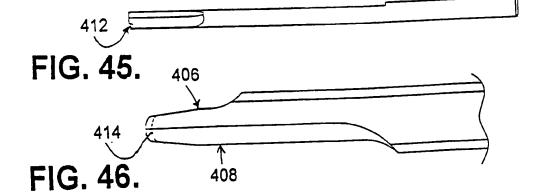
SUBSTITUTE SHEET (RULE 26)

14/16









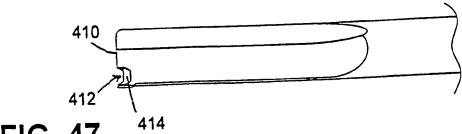
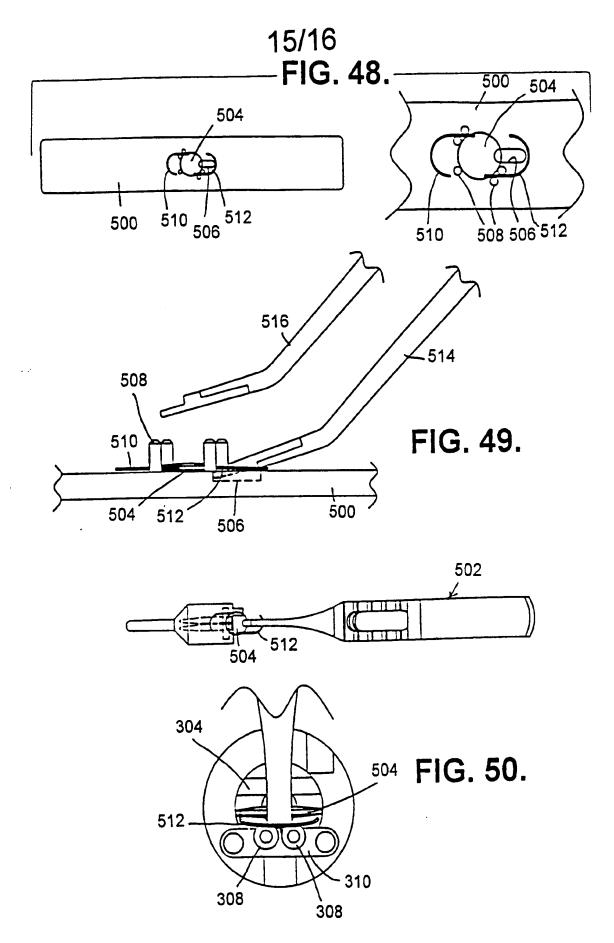


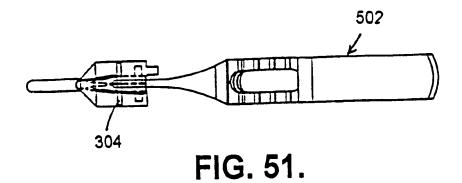
FIG. 47.

PCT/GB99/00216

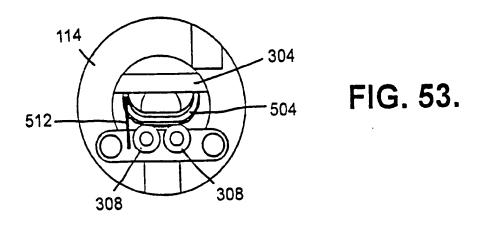


SUBSTITUTE SHEET (RULE 26)

16/16



502 FIG. 52.



INTERNATIONAL SEARCH REPORT

Int Idenal Application No PCT/GB 99/00216

A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61F2/16			
According to	o international Patent Classification (IPC) or to both national classificat	ion and IPC		
	SEARCHED			
Minimum do IPC 6	cumentation searched (classification system followed by classification A61F	n symbols)		
Documental	ion searched other than minimum documentation to the extent that su	ch documents are included in the fields sea	srched	
Electronic d	ata base consulted during the international search (name of data base	e and, where practical, search terms used)		
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT		···	
Category °	Citation of document, with indication, where appropriate, of the rele	vam passages	Relevant to claim No.	
X	US 5 620 450 A (EAGLES DANIEL C 15 April 1997 see column 10, line 35 - column 1	1,10,12		
Α	18; figures		5,7-9,17	
X	WO 96 03924 A (CHIRON VISION CORP; FIGUEROA DENNIS ALEXANDER (US); ALOK (US) 15 February 1996 see page 7, paragraph 1 - page 8,	1,10		
A	paragraph; figures		7,8,17	
Р,Х	WO 98 05281 A (STAAR SURGICAL CO 12 February 1998 see page 16, line 21 - page 17, l		1,10	
A	figures 		7-9	
Furt	her documents are listed in the continuation of box C.	Patent (amily members are listed in	n annex.	
	stegories of cited documents :	Patent family members are listed in T* later cocument published after the inter		
"E" earlier filling of "L" cocume which chatio other "P" docume later t	ent defining the general state of the lart which is not bered to be of particular refevence document but published on or after the international date and which may throw doubts on priority claim(s) or is cited to establish the publication date of another nor other special reason (as specified) ent referring to an oral disclosure, use, exhibition or means ent published prior to the international filing date but han the priority date claimed	or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family Date of mailing of the international search report		
	actual completion of the international search 9 April 1999	10/05/1999		
	mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk	Authorized officer		
	Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Neumann, E		

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int dional Application No PCT/GB 99/00216

Patent document cited in search report		Publication date	F	Patent family member(s)	Publication date
US 5620450	A	15-04-1997	US	5499987 A	19-03-1996
			US	5860984 A	19-01-1999
			AU	4749496 A	24-07-1996
			CA	2208997 A	11-07-1996
			CN	1172421 A	04-02-1998
			EP	0804131 A	05-11-1997
			ĴΡ	10511876 T	17-11-1998
			WO	9620662 A	11-07-1996
			US	5616148 A	01-04-1997
			US	5772666 A	30-06-1998
			AU	4501796 A	17-06-1996
			CA	2181472 A	30-05-1996
			CN	1143313 A	19-02-1997
			EP	0743840 A	27-11-1996
			JP	9508053 T	19-08-1997
			NZ	300333 T	26-06-1998
			WO	9615743 A	30-05-1996
			US	5807400 A	15-09-1998
			US	5728102 A	17-03-1998
			AU	1846395 A	04-09-1995
				2183462 A	24-08-1995
			CA CN	1145580 A	19-03-1997
					17-03-1997
			EP	0901343 A	16-09-1997
			JP	9509086 T	24-09-1998
			NZ	281501 A	
			MO	9522287 A	24-08-1995 11-12-1996
			EP	0746237 A	26-06-1998
			NZ	282170 A 692425 B	11-06-1998
	•		AU		26-04-1994
			AU	5349594 A	13-08-1998
			AU	6197498 A 2144741 C	08-04-1997
			CA	2144741 C 0723429 A	31-07-1996
			EP		18-06-1996
			JP	8505540 T	14-04-1996
			WO	9407436 A	
			US	5494484 A	27-02-1996
			US	5582614 A	10-12-1996
			US	5891152 A	06-04-1999 02-03-1999
			US	5876440 A	02-03-1999
			US	5868751 A	01-09-1998
			US	5800442 A	01-09-1996
WO 9603924	Α	15-02-1996	AU	3214695 A	04-03-1996
			CA	2173609 A	15-02-1996
			EP	0722292 A	24-07-1996
			JP	9506285 T	24-06-1997
			US	5873879 A	23-02-1999
WO 9805281		12-02-1998	US	5876406 A	02-03-1999
MO 3003201	7	15 05 1330	AU	3821097 A	25-02-1998
			ΛU	JOETOS! W	23 02 1330